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Barriers to the use of morphine for the management of severe postoperative pain – A before and after study

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ABSTRACT

Aim: To reduce the number of patients experiencing severe postoperative pain by prescribing 10 mg Morphine either as oral solution or by IM injection as an alternative to Tramadol Hydrochloride in an analgesic protocol.

Materials and methods: Patients who received in-patient oral and maxillofacial surgery under general anaesthesia were included. Complex intervention analgesic protocols were developed including staff education, patient education and analgesic protocols. 80 patients were treated under the original protocol (tramadol hydrochloride for pain unmanaged by other drugs in protocol) over 4 months. 75 patients were treated under the second protocol (oral or intravenous morphine for pain unmanaged by other drugs in protocol). Patient perceptions to their pain management were then assessed.

Results: Proportion of patients reporting 'no pain' increased from 5% of 80 patients to 28% of 75 patients ($p < 0.001$). Report of severe pain reduced from 37% to 31% and not significant. Pain duration reduced from 18% to 12% for 75–100% time from surgery to discharge and not significant. Staff used protocols for 96% patients. Nurses provided patient information leaflets for 85%–80% patients. Nearly all patients (96% and 95%) reported overall satisfaction with their pain management.

Conclusions: The use of morphine given orally or by IM injection rather than tramadol was associated with a significant increase in the number of patients reporting 'no pain'. However the number of patients experiencing severe pain was not significantly reduced. Despite this, most patients reported high levels of satisfaction which suggested that satisfaction questionnaires should not be used in isolation. Most patients received morphine orally rather than by IM injection but the oral dose may not have been high enough in this study.

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1. Introduction

Patient reported outcome measures (PROMs) are gaining global recognition as an important measure of the quality of healthcare. The collection and reporting of PROMs is a key priority in Britain as set out in the Government's 2010 White Paper, Equity and excellence: Liberating the NHS¹ where the commitment was made to 'extend PROMs across the NHS wherever practicable'.⁴ Tools are also being developed to help commissioners (purchasers) of healthcare with easily understandable information and interpretation of PROMs to assist in their health investment decisions.²

Improvements in healthcare are frequently enabled by financial incentives and pressures. If postoperative pain had been an outcome measure of patient care then we may have seen more

research investment in this area and more rapid improvements. A national UK study of hospital in-patients investigated individuals' experiences during their time in hospital back in 1994.³ The results of this study showed that pain management was a major problem with as many as 87% of the 3000 patients involved experiencing pain of moderate or severe intensity. Sadly numerous subsequent studies around the world have highlighted the difficulty of making significant improvement.

An early study by the authors investigating postoperative pain amongst patients undergoing in-patient oral and maxillofacial surgery found that 93% of patients experienced postoperative pain during their hospital stay, 34% of whom experienced severe pain and 47% experienced moderate pain.⁵ Inadequate drug regimes, poor staffing levels and education were cited as possible barriers to delivery of good postoperative pain control. Very few patients received morphine despite it having been prescribed. A later study implemented an evidence-based analgesic drug protocol, staff education and patient education in an attempt to improve the patient

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experience.⁶ Tramadol hydrochloride 50–100 mg was included in this study in the analgesic protocol for the management of severe pain rather than morphine as it has less legal restriction and was more likely therefore to be administered.

The UK legislation classifies morphine as a 'Schedule 2: Controlled Drug and as such is subject to full control'. In addition, individual hospitals may impose additional practice policy that further restricts the accountability and responsibility, requisition, receipt, storage, key holding and access, record keeping, stock checks and discrepancies and administration. Morphine is stored in a designated controlled drug cupboard (a cupboard within a cupboard requiring two keys to gain access) and administration of morphine by injection requires two nurses to be involved and present during the whole administration procedure and this requires good staffing levels and available time that were frequently under pressure. Study patients experiencing pain were usually not given morphine but were asked to wait until their next dose of ibuprofen or paracetamol codeine combination. Fear of addiction and respiratory depression were also suggested as reasons for the under utilisation of morphine. The authors found however that whilst fewer (23%) experienced moderate pain, 81% of patients were still experiencing postoperative pain and 37% experienced severe pain.

The aim of this new study was to reduce the proportion of patients experiencing severe postoperative pain by facilitating the more ready administration of morphine by prescribing a formulation with reduced legal control. Morphine oral solution 10 mg was included in the analgesic protocol as an alternative to morphine for intramuscular injection 10 mg which is the traditional route. Morphine oral solution is classified as a Schedule 5 drug and is stored in a cupboard with a single key and may be administered by one nurse. We also wished to include medical and dental and nursing education in addition to patient education in our study as these had been shown to be effective interventions in earlier studies.^{5,6} Other investigators have previously shown that many patients do not know how effective analgesics can be and think that pain in the inevitable consequence of surgery.^{7,8} Patient misconceptions can be reinforced by health practitioners who lack up-to-date education themselves.^{9,10}

2. Methods

2.1. Study methodology

This was a before and after study. A previous study had demonstrated an improvement in the postoperative pain experience by introducing staff education, an analgesic protocol and patient information but this had little effect on 'severe' pain. In this study we changed the analgesic protocol to include morphine by oral or intramuscular route and measured outcomes before and after the change.

2.2. Participants

All patients, excluding oncology patients, who received in-patient oral and maxillofacial surgery under general anaesthetic were included in the study over a four month period before the changed analgesic protocol and for a four month period after the change at Manchester Royal Infirmary (a hospital of Central Manchester University Hospitals NHS Foundation Trust). All patients were assured of confidentiality of individual data and the study was approved by the Local Research Ethics Committee. Patients were informed of the study immediately prior to ward discharge.

2.3. Intervention

This was a complex intervention consisting of staff education, patient education and use of analgesic protocols. Outcomes were measured before and after the change of analgesic protocol component of the complex intervention as described below. Other components of the intervention remained the same.

A one hour seminar for junior medical/dental staff and for ward nurses was provided. The content of the seminar included pain assessment and management and the current study protocol and clinical pharmacology relevant to the protocol drugs. There was discussion of cultural and educational barriers to delivery of good pain management. The seminar was provided on several occasions to staff ensure access. The same seminar was provided for medical/dental and nursing staff who usually attended as mixed group. A seminar was provided before and after the change to the analgesic protocol.

The 'before change' two protocols included tramadol hydrochloride for pain unmanaged by other drugs in the protocol. The two protocols were changed to those in Table 1. Protocol 1 included ibuprofen. Protocol 2 did not include ibuprofen and was to be used for patients for whom NSAIDs were contraindicated. These were pre-printed protocols available on the ward and requiring a single medical/dental staff signature for prescription. This avoided the need for the clinician to prescribe each protocol drug individually and so simplified the process significantly. The clinician signed off protocol 1 or protocol 2 according to the patient's general health and medical history.

The analgesic protocols were developed from the WHO Pain Ladder using published Systematic Reviews from the Oxford Pain Group.^{10,11}

The previous protocols had included tramadol 50–100 mg orally four hourly as necessary up to 400 mg in 24 h rather than morphine. In the new protocols, tramadol was omitted and replaced with morphine orally or by injections as above.

Patient education was by provision of printed Patient Information Leaflets. These were given to all patients on ward admission and informed them that pain was a normal consequence of surgery but that it could be managed very well. The patient was encouraged to ask for pain relief from the nurses if they experienced any pain.

Table 1

Table showing changed Analgesic Protocols.

Protocol 1	Protocol 2
Ibuprofen 600 mg four times a day (0600, 1200, 1800, 2200)	Paracetamol 1 g/codeine phosphate 30 mg or 60 mg combination four times a day (0600, 1200, 1800, 2200)
If patient continues to experience pain	If patient continues to experience pain
Paracetamol 1 g/codeine phosphate 30 mg or 60 mg combination as necessary four hourly up to 4 times in 24 h	Morphine sulphate for injection 10 mg by intramuscular injection or Morphine sulphate oral solution (sugar free) 10 mg by oral route as necessary four hourly
If patient continues to experience pain	
Morphine sulphate for injection 10 mg by intramuscular injection or Morphine sulphate oral solution (sugar free) 10 mg by oral route as necessary four hourly	

Contraindications to Protocol 1.

- Over 65 years of age
- Pregnancy or breastfeeding
- History of gastro-intestinal bleeding
- History of cardiac impairment
- History of coagulation defect
- Known hypersensitivity to aspirin or other NSAID
- History of worsening asthma with NSAIDs. Patients who had previously used NSAIDs without worsening asthma may be prescribed Protocol 1

The leaflets were provided to all patients before and after the change to the analgesic protocol.

2.4. Outcome measures

The primary outcome measures of interest were the following:

- Patient response to direct questions about their pain management
- Patient response to overall satisfaction with their pain management
- Protocol analysis

The questionnaire comprised the following three sections.

1. Demographics

Personal details including age and sex.

2. Pain management

A series of specific questions about the patient's pain management. Pain severity and duration were measured using visual analogue scales (VAS). These 10 cm scales described 'no pain' to 'worst pain imaginable', and 'none of the time' to 'all of the time'. These values were converted to 4-point categorical descriptions for analysis.¹³

3. Patient satisfaction

A general question about overall satisfaction with the pain control received.

Each patient was interviewed immediately prior to discharge by a researcher. A study information sheet was presented and any questions answered and the patient was asked to complete a consent form to confirm their understanding of the study. Part 1 of the study questionnaire was completed by the researcher and the patient was asked to complete parts 2 and 3.

Secondary outcome measures were: nature of the surgery that has been undertaken; which protocol selected for prescription; reason(s) for selection of protocol 2; reasons for not selecting either protocol; alternate analgesics prescribed if neither protocol selected; and time taken to receive medication requested.

2.5. Data analysis

Data were analysed using Statistical Package for the Social Sciences (SPSS) and tested for normality where appropriate using the Kolmogorov–Smirnov test. Student's *t*-test or 1-way ANOVA followed by post-hoc Turkey's test was used and differences between groups analysed using chi-square tests. Collins et al.¹³ found that a VAS score of 30 mm or above was equivalent to moderate pain whilst a VAS score of 54 mm or above was equivalent to severe pain. The VAS codes were re-coded using these boundaries to four categories, none, mild, moderate and severe pain.

2.6. Demographics and group characteristics

There were a total of 80 patients in the study before the changed analgesic protocol and 75 patients after the change. There was no significant difference in the proportion of male and females in the before and after groups with 112 (72%) males and 43 (28%) females in total. There was no significant difference between groups for age and a mean age of 34 years (range 16–76 years).

Trauma surgery was the most frequent type of surgery for both groups. There was no significant difference in the type of surgery between the before and after analgesic protocol change (Table 2).

Table 2

Table showing pain severity at its worst before and after the analgesic protocol change.

Pain severity at its worst	Before protocol change	After protocol change
None	4 (5%)	21 (28%)
Mild	29 (36.3%)	16 (21%)
Moderate	18 (22.5%)	15 (20%)
Severe	29 (36.6%)	23 (31%)
Total	80 (100%)	75 (100%)

There was a significant sex difference for type of surgery, with 68.5% males having surgery due to trauma and only 14.3% of females having surgery for this reason ($P = 0.00$). There was no statistical difference between the severity of pain or frequency of pain experienced and the type of surgery performed, ethnic origin or social class.

3. Results

3.1. Pain outcomes

Most patients experienced some postoperative pain during their stay in hospital with 95% before the change and 72% after the change in analgesic protocol. The increase in the proportion of patients reporting 'no pain' after the change (28%) compared to before (5%) was statistically significant ($p < 0.001$). There was an improvement after the analgesic protocol change in reported worst pain as mild, moderate and severe pain but these changes were not statistically significant (Table 3).

In the 'after protocol change' group 43% patients (60% of all who experienced postoperative pain) reported their first experience of pain as being within the first four hours of recovery from anaesthesia for surgery (Fig. 1). The same pattern was observed for the group before protocol change with no statistically significant difference. Approximately 12% of patients experienced pain for from three-quarters to all of the time from surgery to hospital discharge. The duration of the patient pain experience is shown in Fig. 2. The median length of time for which pain was experienced was 27% (SD = 29.40) of the time from surgery to discharge. There were fewer patients experiencing pain for more than 50% of the time from operation to discharge after the protocol change (Table 4). However this observation was not statistically significant.

A larger proportion of females (81%) than males (68%) in the study group experienced some postoperative pain but this difference was not statistically significant. For the majority of patients that did experience postoperative pain, there was no significant difference between females and males for the pain severity category.

Patients under the age of 33 years recorded significantly more moderate pain than those aged 33 years or more (Table 5). There was no significant difference for no pain or other categories of pain severity.

Table 3

Table showing number of patient experiencing pain for proportion of time from surgery to discharge by group before and after change in analgesic protocol.

Duration of pain from surgery to discharge	Number of patients before protocol change	Number of patients after protocol change
0%–24%	34 (43%)	35 (47%)
25%–49%	16 (20%)	22 (29%)
50%–74%	16 (20%)	9 (12%)
75%–100%	14 (18%)	9 (12%)
Total	80 (100%)	75 (100%)

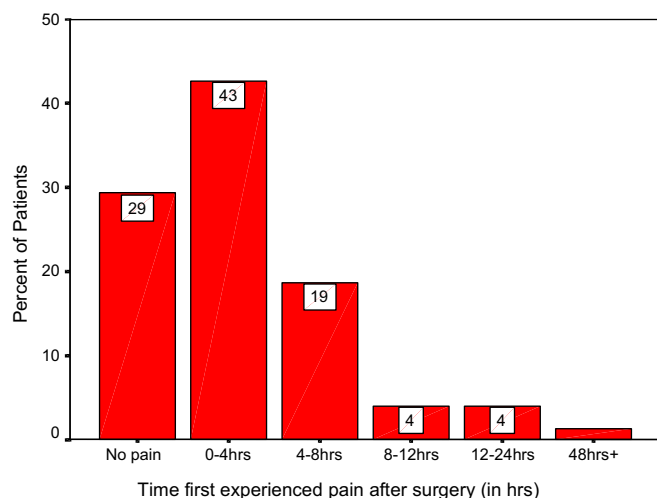


Fig. 1. Bar chart showing time of patient report of start of postoperative pain for group after change of analgesic protocol.

3.2. Patient experience and satisfaction

Patient request for additional analgesics was by 33% of the before change group and 39% of the after change group. Of these, 75% in the before group and 79.3% in the after group waited less than 15 min to receive them with the remainder receiving the analgesics within 30 min.

When patients were asked about their expectations of pain, 20% before changing the protocol and 24% after the change, reported that their pain was worse than expected. This difference was not statistically significant.

All ward nursing staff were asked to provide every oral and maxillofacial surgery inpatient with the patient information leaflet about pain management. When asked about this, 85% of the before change group and 80% of the after change group remembered being given this leaflet.

When patients were asked at the time of hospital discharge about their overall experience of pain management, 96% of the before change group and 95% of the after change group reported that they were satisfied with the pain control they received.

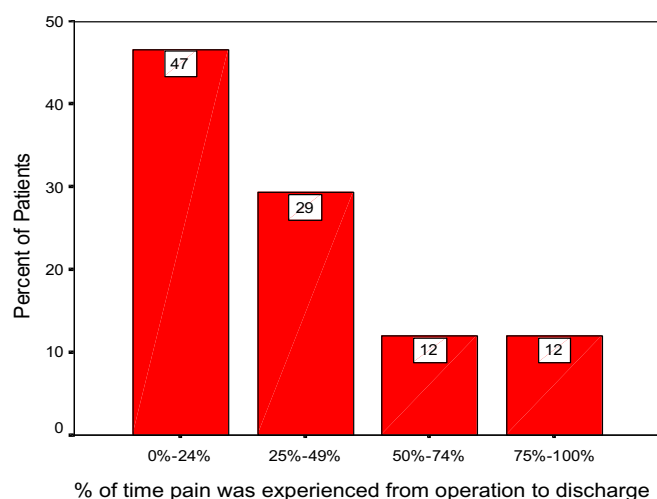


Fig. 2. Bar chart showing duration of pain experienced from surgery to hospital discharge for the after analgesic protocol change group.

Table 4

Table showing proportion reporting different pain severities by age.

Pain severity at its worst	Age < 33 years	Age > 33 years
None	20.4%	32.4%
Mild	20.4%	17.6%
Moderate	26.5%	5.9%
Severe	32.7%	20.6%
Total	100%	100%

3.3. Analgesic protocol

Only 4% of patients were not prescribed either of the protocols. Reasons were described as, prescription changed by anaesthetist, patient request and staff error. Protocol 1 was prescribed for 78.7% of the study population and protocol 2 for 17.3%. Protocol 2 was used most frequently where patients had a history of gastrointestinal ulceration. Asthma and coagulation defect accounted for a smaller number.

There was no particular pattern in the pain relief prescribed for the patients who did have protocol 1 or 2 prescribed. Prescriptions included tramadol hydrochloride 100 mg only and paracetamol only. For those prescribed Protocol 1 or 2, Morphine sulphate oral solution was administered on at least occasion to 32% of patients and Morphine sulphate by injection to 3% of patients.

More patients (23.7%) prescribed protocol 1 reported moderate pain than those prescribed protocol 2 (7.7%). However this difference was not statistically significant and there was less difference for other categories of pain severity (Table 6).

4. Discussion

The 'before' and 'after the protocol change' groups were balanced for sex, age and type of surgery. Introducing morphine oral solution and morphine by intramuscular injection was associated with a significant increase in the number of patients experiencing 'no pain' compared to use of tramadol hydrochloride. There was an improvement in reported worst pain as 'mild', 'moderate' and 'severe' but these changes were modest and not statistically significant. However these modest changes in each of these categories of pain severity account perhaps for the larger number experiencing 'no pain'. It was disappointing that the number of patients experiencing 'severe pain' was not significantly reduced as this was the aim of this particular study. A previous study by the authors had already demonstrated improvement in the patient's pain experience after surgery by introducing staff and patient education and an analgesic protocol.⁶ This new study was therefore going to be challenged in demonstrating an even greater improvement. As it is clearly important for morphine to be regulated as a Schedule 2: Controlled Drug, it is necessary to consider how any barriers can be overcome to ensure that this drug can be administered to patients who need it. The previous study included tramadol hydrochloride rather than morphine because of concerns

Table 5

Table showing frequencies of surgery by type.

Type of surgery	Before	After
Dentoalveolar	19 (23.8%)	16 (21.3%)
Orthognathic	4 (5%)	2 (2.7%)
TMJ	1 (1.3%)	4 (5.3%)
Trauma	38 (47.5%)	40 (53.3%)
Salivary	3 (3.8%)	3 (4%)
Other	15 (18.8%)	10 (13.3%)
Total	80 (100%)	75 (100%)

Table 6

Table showing pain severity reported by protocol.

Pain severity at worst	Protocol 1	Protocol 2	Neither Protocol
None	27.1%	38.5%	0
Mild	22.0%	24.1%	0
Moderate	23.7%	7.7%	0
Severe	27.1%	30.8%	100%
Total	100%	100%	100%

shown in an earlier study that nursing staff resisted administering morphine because of the time consuming procedural issues around administering controlled drugs. Tramadol however had not demonstrated a significant reduction in the number of patients experiencing severe pain. In this study our hypothesis was that by including morphine as *oral solution* which requires less complex procedural processes for administration, this might remove one of the barriers to the administration of morphine on a more frequently basis for severe pain.

In the authors' early study only 1.5% of patients received morphine that was prescribed for intramuscular injection although another 4% received morphine via a patient controlled analgesic system.⁵ In this current study a much larger proportion of patients did receive morphine and most of these received it by the oral route (32%) rather than the intramuscular injection route (3%). This was a successful outcome of this study and suggests that the procedural processes around the administration of morphine are indeed a barrier to improving pain management. Perhaps it did not have the impact hoped for on managing severe pain because of dose limitations. We had introduced a dose of 10 mg by intramuscular route and also a 10 mg dose by the oral route for reasons of simplicity and safety. However, this oral dose may have been inadequate.

There was a high rate of medical and dental clinical staff complying with prescription of the analgesic protocols which was another success of this study. The use of protocols for prescribing required less staff time. The assumption that oral morphine was administered more frequently than intramuscular injection because of the reduced controlled drug procedural barrier may not be the complete answer. We do not know if medical, dental and nurse education had been effective or not in encouraging the use of morphine where necessary. If so, then this may have been the explanation of greater use of morphine. However, perhaps there was still a misunderstanding that intramuscular morphine was less safe than oral morphine. It is recognised that clinicians may fear addiction and respiratory depression.¹² Addiction is not a problem in acute pain management and titration of morphine against pain relief avoids respiratory depression.^{12,14}

A future study could encourage the use intramuscular morphine which has a known effectiveness for severe postoperative pain¹⁵ by further exploring staff attitudes, knowledge and understanding. Patient attitudes, knowledge and understanding of opioids should also be explored in addition to their confidence and trust in their health practitioners.¹⁶

Pain developed rapidly after surgery with 43% of patients experiencing pain within 4 h. It is usual practice to use intra-operative local anaesthesia whenever possible so it was interesting to find that pain developed so soon. We did not investigate the choice of local anaesthesia used in this study. Use of bupivacaine that offers anaesthesia for 6–8 h would be the obvious choice for management of postoperative pain.¹⁷

Whilst there were fewer patients experiencing pain for more than 50% of the time from operation to discharge after the protocol change, it was of concern that about 12% of patients experienced pain for from three-quarters to all of the time from surgery to hospital discharge.

There was no significant difference in the experience of male and females although younger patients under 33 years did report significantly more moderate pain than those aged 33 years or more. There was no significant difference for no pain or other categories of pain severity. Other studies had reported less pain being reported by older patients.^{18,19} The study group had a majority of male patients and this was because a significant proportion of patients were admitted for oral and maxillofacial trauma surgery as this is associated with male interpersonal violence in the Central Manchester patient capture area. There was no statistical difference between the severity of pain or duration of pain experienced and the type of surgery performed, ethnic origin or social class.

Whilst the majority of patients received analgesics within 15 min of requesting them, about 25% received them with 30 min. Is this good practice or not? Perhaps it would be preferable for a more proactive practice to be place such that analgesia is administered against an anticipated need rather than awaiting request. However, the philosophy of our protocols was in line with the WHO pain ladder in that simple analgesics are administered early on a regular basis and others administered when required. Not all patients will require morphine and so it would be inappropriate to administer on a regular basis rather than when necessary basis. Another problem can be the reluctance of patients to allow regular administration of analgesics to manage pain and prevent breakthrough pain. In a study by Owen et al.²⁰ two-thirds of patients said they would wait until they were in severe pain before requesting analgesia or would not ask at all. This has implications in terms of reducing the incidence of severe pain, as it is easier to prevent pain occurring rather than treat it once it has developed.²¹ Other studies²² have also reported on patients' reluctance to request analgesia, with one study²³ describing 64% of patients who had suffered pain outlasting the first postoperative day not informing staff. It has also been reported that patients themselves perceive risks with postoperative analgesia, particularly regarding addiction to opioids, and may be reluctant to seek pain relief for this reason. One way to circumvent this problem could be to use patient controlled analgesia (PCA). However, the effectiveness of PCA using morphine in maxillofacial surgery has been questioned in a study by Foley et al.²⁴ in which severe pain was not controlled successfully and the rate of emesis was unacceptably high. In our study we introduced provision of patient information leaflets to encourage patient to take responsibility for their own pain management and to encourage them to actively seek analgesia from nursing staff. All ward nursing staff were asked to provide every oral and maxillofacial surgery inpatient with the patient information leaflet about pain management. However, when asked about this, around 15–20% did not recall being given this leaflet. It is obviously essential that all patients do receive the leaflet but provision needs to take account of work demands in the clinical area and needs appropriate hospital policy.²⁵ Hawkins and Price²⁶ have suggested that the routine use of a good quality patient pain management information video may help provide patients with the confidence to ask for extra pain relief before they are in severe pain.

When patients were asked about their expectations of post-operative pain, 20% of patients reported that their pain was worse than expected. The difference after the analgesic protocol change (24%) was not statistically significant. Perhaps this is not surprising as patients had reported poor postoperative pain management in response to direct, specific questions in this regard. However, when patients were asked at the time of hospital discharge about their overall experience of pain management, 96% of the before change group and 95% of the after change group reported that they were satisfied with the pain control they received. One would anticipate that poor pain management would have a negative impact on patient satisfaction but this was not the case.²⁷ This would tend to

suggest that patients' expectations in relation to pain management were low and that results from satisfaction questionnaires should not be used in isolation. This is an important consideration in the development of PROMs. Finally, whilst this study concentrated mainly on the control of pain through the use of drugs it is important to note that effective control of pain relies on several basic concepts from clinical psychology such as self-control, coping and self-efficacy.²⁸ Most hospital settings do not support any sort of activity that encourages patients to cope for themselves²⁹ but a Patient Information Leaflet is one mechanism.

5. Conclusions

In conclusion, nearly all patients reported that they were satisfied overall with the pain control, though many experienced severe pain. This may be because the oral dose of morphine was inadequate. In addition, this suggests that results from satisfaction questionnaires should not be used in isolation.

Ethical approval

Ethical approval was given by the Local research ethics committee at The University of Manchester, Manchester, UK.

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Author contribution

Paul Coulthard – Study Lead.

Neil Patel – data analysis + writing.

Edmund Bailey – data analysis + writing.

Debra Armstrong – data collections.

Conflict of interest

This study was not funded and there are no conflicts of interest.

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